

EXPRESS MAIL LABEL NO.: EV 525254075 US DATE: 11/7/05**IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)**

Applicants: John Donnelly et al.
Application No.: 10/530,543
International Application No.: PCT/US2003/031935
International Filing Date: October 7, 2003
Title: HIV VACCINE FORMULATIONS
Examiner: To Be Assigned
Group Art Unit: To Be Assigned
Confirmation No.: 4724
Attorney Docket No.: PP19844.0003

INFORMATION DISCLOSURE STATEMENT (IDS)**MAIL STOP PCT**

Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with 37 C.F.R. §1.56 and in compliance with 37 C.F.R. §§1.97 and 1.98, the references listed on attached Form PTO-1449 and/or subsequently identified herein, are being submitted herewith for consideration by the United States Patent and Trademark Office.

I. COPIES

- a. ☒ A legible copy of (i) each foreign patent; (ii) each publication or that portion which caused it to be listed; and (iii) all other information or that portion which caused it to be listed, is included herewith.
- b. ☐ Any patents, publications or other information which are listed on Form PTO-1449 which are not enclosed herewith were previously cited by or submitted to the PTO in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. §120:

U.S. Application NumberU.S. Filing Date**II. CONCISE EXPLANATION OF THE RELEVANCE (check at least one box)**

- a. ☒ Except as may be indicated below in (b) of this section, all of the patents, publications or other information are in the English language (concise explanation not required).
- b. ☐ A concise explanation of the relevance of all patents, publications or other information listed that is not in the English language is as follows:
- c. ☐ The following additional information is provided for the Examiner's consideration:

III. ☐ CROSS REFERENCE TO RELATED APPLICATION(S)

The Examiner is advised that the following co-pending application(s) contain(s) subject matter that may be related to the present application. By bringing this (these) applications to the Examiner's attention, Applicant(s) does(do) not waive the confidentiality provisions of 35 U.S.C. §122.

Application No. _____

Filing Date _____

Art Unit _____

FEES

- IV. ☐ **THIS IDS IS BEING FILED UNDER 37 C.F.R. §1.97(b):** (check one box)
- a. ☐ within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d) (37 C.F.R. §1.97(b)(1)). No fee or statement is required.
 - b. ☐ within three months of the date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. §1.97(b)(2)). No fee or statement is required.
 - c. ☒ before the mailing date of a first Office Action on the merits (37 C.F.R. §1.97(b)(3)). No fee or statement is required.
 - d. ☐ before the mailing date of a first Office Action after the filing of a request for continued examination under § 1.114 (37 C.F.R. § 1.97(b)(4)). No fee or statement is required.
- V. ☐ **THIS IDS IS BEING FILED UNDER 37 C.F.R. §1.97(c):** (check one box)
- before the mailing date of any of a Final Office Action under 37 C.F.R. §1.113, a Notice of Allowance under 37 C.F.R. §1.311, or an action that otherwise closes prosecution in the application (See 37 C.F.R. §1.97(c)).
- a. ☐ No statement; therefore, charge deposit account _____ the fee set forth in 37 C.F.R. §1.17(p).
 - b. ☐ See the statement below. No fee is required.
- VI. ☐ **THIS IDS IS BEING FILED UNDER 37 C.F.R. §1.97(d):**
- on or before payment of the issue fee and is accompanied by the following:
- 1) a statement under 37 C.F.R. §1.97(e) as provided below; and
 - 2) charge deposit account _____ the petition fee set forth in §1.17(p).
- VII. ☐ **STATEMENT UNDER 37 C.F.R. §1.97(e)** (check only one box, if applicable)
- The undersigned hereby states that
- a. ☐ each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of IDS; or
 - b. ☐ no item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application, and to knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the IDS was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this statement, or
 - c. ☐ some of the items of information contained in the IDS were cited in a communication from a foreign Patent Office. As to this information, the undersigned states that each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby states that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application or, to the knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the IDS was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this statement.

VIII. PAYMENT OF FEES

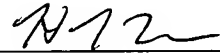
- ☐ Check in the amount of _____ is enclosed for the above-identified fee(s).
☐ Please charge Deposit Account No. _____ in the amount of \$180.00 for the above-indicated fee(s).
☒ If Applicant has overlooked any additional fees, or if any overpayment has been made, the Commissioner is hereby authorized to credit or debit Deposit Account 03-1664.
☐ Two Copies of this paper are attached for Deposit Account charges and debits.

It is Applicant(s)' opinion that the claims presently on file patently distinguish the present invention from each of these references. The above references are being cited only in the interests of candor and without any admission that they constitute statutory prior art or contain matter which anticipates the invention or which would render the same obvious, either singly or in a combination, to a person of ordinary skill in the art.

If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule (with a petition if necessary) and charge the appropriate fee to Deposit Account No. 03-1664.

Respectfully submitted,

By



Helen Lee
Registration No. 39,270
Tel: (510) 923-2192
Fax: (510) 655-3542

CHIRON CORPORATION
Customer Number 27476

Enclosures: ☒ PTO-1449 Form (1 sheet)
☒ References (B1-B7, C1-C4)
☐ Search Report
☐ Other:

THE UNITED STATES PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT PTO-1449 FORM (MODIFIED) SHEET 2 OF 2	ATTORNEY DOCKET NO. PP19844.0003	INTERNATIONAL APPLICATION NO. PCT/US2003/031935
	FIRST NAMED INVENTOR John Donnelly	EXAMINER To Be Assigned
	INTERNATIONAL FILING DATE October 7, 2003	
	CONFIRMATION NO. 4724	GROUP ART UNIT To Be Assigned

FOREIGN PATENT DOCUMENTS						
EXAMINER INITIAL	REF. NO.	DOCUMENT NUMBER	PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION YES NO	
	B1	WO 01/52886 A1	07-26-2001	Alfred Hospital et al.		
	B2	WO 98/33487	08-06-1998	Chiron Corporation		
	B3	WO 00/06123	02-10-2000	Chiron Corporation		
	B4	WO 02/26212	04-04-2002	Chiron Corporation		
	B5	WO 02/26209	04-04-2002	Chiron Corporation		
	B6	WO 04/065578	08-05-2004	Chiron Corporation		
	B7	WO 99/30737	06-24-1999	Chiron Corporation		

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)		
EXAMINER INITIAL	REF. NO.	DESCRIPTION
	C1	Srivastava, I. et al., "Purification, Characterization, and Immunogenicity of a Soluble Trimeric Envelope Protein Containing a Partial Deletion of the V2 Loop Derived from SF162, an R5-Tropic Human Immunodeficiency Virus Type 1 Isolate," <i>J. Virol.</i> 77(20):11244-11259 (2003).
	C2	Barnett, S.W. et al., "The Ability of an Oligomeric Human Immunodeficiency Virus Type 1 (HIV-1) Envelope Antigen To Elicit Neutralizing Antibodies against Primary HIV-1 Isolates Is Improved following Partial Deletion of the Second Hypervariable Region", <i>J. Virol.</i> 75(12):5526-5540 (2001).
	C3	Srivastava, I. et al., "Purification and Characterization of Oligomeric Envelope Glycoprotein from a Primary R5 Subtype B Human Immunodeficiency Virus", <i>J. Virol.</i> 76(6):2835-2847 (2002).
	C4	Jeffrey, H. et al., "The Preparation and Characterization of Poly(lactide-co-glycolide) Microparticles. II. The Entrapment of a Model Protein Using a (Water-in-Oil)-in-Water Emulsion Solvent Evaporation Technique", <i>Pharm. Res.</i> 10(3):362-368 (1993).

EXAMINER'S SIGNATURE	DATE CONSIDERED
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THE UNITED STATES PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT PTO-1449 FORM (MODIFIED) SHEET 1 OF 2	ATTORNEY DOCKET NO. PP19844.0003	INTERNATIONAL APPLICATION NO. PCT/US2003/031935
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U.S. PATENT DOCUMENTS				
EXAMINER INITIAL	REF. NO.	DOCUMENT NUMBER	ISSUE DATE/ PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	A1	5,643,605	07-01-1997	Cleland et al.
	A2	5,603,960	02-18-1997	O'Hagan et al.
	A3	US2003/0191076 A1	10-09-2003	Wesselingh et al.
	A4	6,884,435	04-26-2005	O'Hagan et al.
	A5	US2003/0049298 A1	03-13-2003	O'Hagan et al.
	A6	US2004/0022814 A1	02-05-2004	O'Hagan et al.
	A7	US2005/0191319 A1	09-01-2005	O'Hagan et al.
	A8	6,753,015	06-22-2004	Fang et al.
	A9	US2004/0156913	08-12-2004	Fang et al.
	A10	US2003/0138453 A1	07-24-2003	O'Hagan et al.
	A11	US2005/0191358 A1	09-01-2005	O'Hagan et al.
	A12	6,086,901	07-11-2000	O'Hagan et al.
	A13	6,306,405	10-23-2001	O'Hagan et al.
	A14	6,458,370	10-01-2002	O'Hagan et al.
	A15	6,855,492	02-15-2005	O'Hagan
	A16	US2005/0136073 A1	06-23-2005	O'Hagan et al.
	A17	6,602,705	08-05-2003	Barnett et al.
	A18	US2003/0223964 A1	12-02-2003	Barnett et al.
	A19	US2003/0194800 A1	10-16-2003	Megede et al.
	A20	US2003/0170614 A1	09-11-2003	Megede et al.
	A21	US2005/0214256 A1	09-29-2005	Megede et al.
	A22	US2003/0198621 A1	10-23-2003	Megede et al.

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